

§ 341.70

ingredient identified or any combination of anesthetic/analgesic active ingredients and any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to § 341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth.

[67 FR 78168, Dec. 23, 2002]

Subpart C—Labeling

§ 341.70 Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product).

The statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *For products containing diphenhydramine citrate and diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6).* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antihistamine/cough suppressant” or “antihistamine/antitussive (cough suppressant).” The indications shall be combined from §§ 341.72(b) and 341.74(b). The warnings shall be combined from §§ 341.72(c)(1), (c)(2), (c)(4), and (c)(6) and 341.74(c)(1), (c)(2), (c)(3), and (c)(4). Alternatively, all of the warnings in § 341.74(c) shall be used. The directions for OTC labeling shall follow §§ 341.74(d)(1)(iv) or (d)(1)(v), as applicable. The directions for professional labeling shall follow § 341.90(j) or (k), as applicable.

(b) *For products containing menthol identified in §§ 341.14(b)(2) and 356.12(f) of this chapter.* The product contains 5 to 10 milligrams menthol. The labeling of the product contains the established name of the drug, if any, and identifies the product as a “cough suppressant/oral anesthetic” or “antitussive (cough suppressant)/oral anesthetic.” The in-

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dications shall be combined from § 341.74(b) and part 356 of this chapter. The warnings shall be combined from § 341.74(c)(1), (c)(2), and (c)(3) and part 356 of this chapter. The directions shall be: “Directions [in bold type] [bullet]¹ adults and children 2 years and over: dissolve lozenge slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor. [bullet] children under 2 years of age: ask a doctor”.

[61 FR 15703, Apr. 9, 1996, as amended at 67 FR 78170, Dec. 23, 2002; 68 FR 17881, Apr. 14, 2003]

§ 341.72 Labeling of antihistamine drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antihistamine.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” any of the phrases listed in paragraph (b) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) “Temporarily” (select one of the following: “relieves,” “alleviates,” “decreases,” “reduces,” or “dries”) “runny nose and” (select one of the following: “relieves,” “alleviates,” “decreases,” or “reduces”) “sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever” (which may be followed by one or both of the following: “or other upper respiratory allergies” or “(allergic rhinitis)”).

(2) “For the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever” (which may be followed by one or both of the following:

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.